IN THE CLAIMS

Cancel claims 1-44.

45. (New) A stable pharmaceutical composition comprising a therapeutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug or a pharmaceutically acceptable salt, solvate or derivative thereof selected from the group consisting of:

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid 0.2 hydrate; and

RS-(+-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid; and

a pharmaceutically acceptable solubilizing agent selected from the group consisting of basic amino acids, cyclodextrin, a cyclodextrin polymer; or a mixture thereof;

wherein the concentration of the drug that is maintained in solution with the solubilizing agent is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not in solution with the solubilizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

46. (New) The composition of claim 45, wherein the concentration of the drug is about 1 mg/ml to about 100 mg/ml.

47. (New) The composition of claim 45, wherein the concentration of the drug is about

4 mg/ml to about 12 mg/ml.

48. (New) The composition of claim 45, wherein the concentration of the drug is about 5 mg/ml to about 9 mg/ml.

49. (New) The composition of claim 45, wherein the amino acid is selected from the group consisting of arginine, histidine, arginine acetate, arginine-glutamate, arginine monohydrochloride, histidine acetate, histidine acetate dihydrate, histidine monohydrochloride, histidine monohydrochloride monohydrate, lysine, lysine acetate, lysine monohydrochloride, ornithine and, tryptophan; a salt thereof; or a mixture thereof.

50. (New) The composition of claim 45, wherein the amino acid is L-arginine.

51. (New) The composition of claim 45, wherein the cyclodextrin polymer is selected from the group consisting of α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, and hydroxypropyl β-cyclodextrin.

52. (New) The composition of claim 45, wherein the cyclodextrin polymer is hydroxypropyl β-cyclodextrin.

53. (New) The composition of claim 45, wherein the solubilizing agent comprises from about 1.5 % to about 3.5 % by weight of the composition.

54. (New) The composition of claim 45, wherein the solubilizing agent is an amino acid and comprises about 0.1 % to about 1.4 % by weight of the composition.

55. (New) The composition of claim 45, wherein the solubilizing agent is cyclodextrin polymer and comprises about 1.5 % to about 3.5 % by weight of the composition.

56. (New) The composition of claim 45, that is suitable for parenteral administration.

57. (New) The composition of claim 45, that is suitable for intravenous injection or infusion.

58. (New) The composition of claim 45, that is in a physical form selected from a concentrate, lyophilisate, powder, solution, or suspension.

59. (New) The composition according to claim 45 wherein the drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt.

60. (New) The composition of claim 45 wherein the drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid.

61. (New) The composition of claim 59 wherein the solubilizing agent is an amino acid and is L-arginine.

62. (New) The composition of claim 60 wherein the solubilizing agent is an amino acid and is L-arginine.

63. (New) The composition of claim 61 that is suitable for parenteral administration.

64. (New) The composition of claim 61 that is suitable for intravenous injection or infusion.

65. (New) The composition of claim 62 that is suitable for parenteral administration.

66. (New) The composition of claim 62 that is suitable for intravenous injection or infusion.

67. (New) The composition of claim 45, that is in a physical form selected from a concentrate, lyophilisate, powder, solution, or suspension.

68. (New) A stable pharmaceutical composition comprising a therapeutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug or a pharmaceutically acceptable salt, solvate or derivative thereof selected from the group consisting of:

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid 0.2 hydrate; and

RS-(+-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid; and

a pharmaceutically acceptable solubilizing agent selected from the group consisting of basic amino acids, cyclodextrin, a cyclodextrin polymer or a derivative thereof; or a mixture thereof;

wherein the concentration of the drug that is maintained in solution with the solubilizing agent is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not in solution with the solubilizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

69. (New) A method of treating a bacterial infection disease in a subject in need thereof which comprises administering to the subject, a pharmaceutical composition of claim 45 in a therapeutically or prophylactically effective dose.

70. (New) The method of claim 69, wherein the composition is diluted in a pharmaceutically acceptable liquid prior to being administered to the subject.

71 (New) The method of claim 69, wherein the subject is a human or animal subject.

72. (New) The method of claim 69, wherein the daily dose of the benzoquinolizine-2-carboxylic acid antimicrobial drug is about 0.01 mg to 100 mg/kg.

73. (New) The method of claim 69, wherein said solubilizing agent is selected from the group consisting of amino acids, cyclodextrin polymers or a derivative thereof; or a mixture thereof.

74. (New) The method of claim 69, wherein said composition is administered by intravenous injection or infusion.

75. (New) The method of claim 69, wherein the route of administration is parenteral.

76. (New) The method of claim 69, wherein said composition is in a concentrate, lyophilized powder, solution or suspension form.

77. The method composition according to claim 69, wherein the composition comprises S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt.

78. The method according to claim 69, wherein the composition comprises S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

79. The method according to claim 77, wherein the solubilizing agent is an amino acid and is L-arginine.

80. The method according to claim 78, wherein the solubilizing agent is an amino acid and is L-arginine.

81. (New) A process for preparing a pharmaceutical composition comprising: mixing a pharmaceutically

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid 0.2 hydrate; and

RS-(+-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

and a pharmaceutically acceptable solubilizing agent selected from the group consisting of basic amino acids, a cyclodextrin and, a cyclodextrin polymer or a derivative thereof; or a mixture thereof; wherein the concentration of the solubilizing agent is sufficient to maintain the drug in solution at a drug concentration that is above the practical limit of solubility of the drug as compared to the solubility of the drug when the drug is not in solution with the solubilizing agent, wherein the solution is a substantially isotonic aqueous solution at a physiologically compatible pH.

82. (New) The process of claim 81, wherein said solubilizing agent is selected from the group consisting of amino acids, cyclodextrin polymers or a derivative thereof, or a mixture thereof.